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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,043	12/15/2003	Bruce E. Reidenberg	02755/100J533-US1	4015

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EXAMINER

KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/736,043

Applicant(s)

REIDENBERG ET AL.

Examiner

Sharon E. Kennedy

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/16/04; 04/21/04; 05/05/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Claim Rejections - 35 USC § 112

Claims 40 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 40, one cannot refer back to the specification for the information. The figure must be reproduced in the claim.

Regarding claim 45, in view that the independent claim recites a transdermal delivery, the group is not appropriate. Transmucosal and transdermal are not analogous and neither one is a subset of the other. Dermal means skin and the drug goes through the skin. Mucosal means delivery through a mucous membrane, such as the mouth, nose, intrarectally, etc.

Double Patenting

Claims 1-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/736,049. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of this application overlap the claims of the '049 application in that each set of claims are directed to administering a specific dosage of buprenorphine to achieve pain relief via transdermal

administration. Of particular note is the similarity of this application's claim 1 to the '049 application claim 4. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

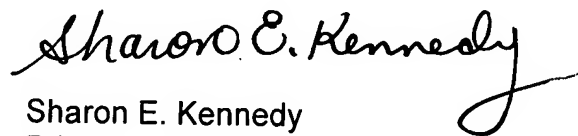
Claim Rejections - 35 USC § 103

Claims 1-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hille et al., US 5,240,711. Hille exemplifies the fact that the administration of transdermal buprenorphine is already very well known. Hille discloses a 24 hour patch, however, it cannot be considered patentable to re-administer a drug dosage over time to treat chronic pain or pain that lasts more than a few days. The various formulations and time periods are considerations that any pain doctor undertakes in the normal routine of doing business with chronically ill patients on a daily basis. Further, even the ordinary consumer understands the concept of treating pain. Bottles of pain killers such as a bottle of aspirin do not come in one aspirin per bottle. In contrast, when one purchases a bottle of aspirin, the medicine is taken as needed for a single episode such as a minor headache, or over time for longer periods such as a sprained wrist or menstrual cramps, with the consumer adjusting the strength/dosage of the pain killer as necessary. In the absence of a showing of surprising results, the claimed dosages are nothing more than a routine description of common pain management practices known by anyone who has ever taken aspirin for a headache.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

A handwritten signature in black ink that reads "Sharon E. Kennedy". The signature is written in a cursive style with a large, stylized "S" and "K".

Sharon E. Kennedy
Primary Examiner
Art Unit 1615